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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,475	01/22/2002	Alexander Gaiger	014058-014402US	3551

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

<b>Office Action Summary</b>	<b>Application No.</b> 10/057,475	<b>Applicant(s)</b> GAIGER ET AL.	
	<b>Examiner</b> Joyce Tung	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 3-4, and 13 drawn to polynucleotide and the composition containing the polynucleotide, classified in class 536, subclass 23.1.
  - II. Claims 2, and 13 drawn to polypeptide and the composition containing the polypeptide, classified in class 530, subclass 350.
  - III. Claim 5, 13 and 18 drawn to antibody and the composition containing the antibody, classified in class 530, subclass 387.1.
  - IV. Claim 6, drawn to a method of detecting the presence of a cancer, classified in class 435, subclass 7.
  - V. Claim 7-9, and 13 drawn to fusion protein and the composition containing the fusion protein, classified in class 435, subclass 69.7.
  - VI. Claims 10 and 17, drawn to an oligonucleotide and the kit containing the oligonucleotides, classified in class 536, subclass 24.3.
  - VII. Claim 11, drawn to a method of stimulating T cells or expanding T cells specific for a tumor protein.
  - VIII. Claim 12-13, drawn to an isolated T cell population and the composition containing the T cell population, classified in class 424, subclass 93.71.
  - IX. Claim 14, drawn to a method of stimulating an immune response in a patient, classified in class 514, subclass 2.

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- X. Claim 15, drawn to a method of treating a cancer in a patient, classified in class 424, subclass 184.1.
- XI. Claim 16, drawn to a method for determining the presence of a cancer in a patient via hybridization classified in class 435, class 6.
- XII. Claim 19, drawn to a method of inhibiting the development of a cancer in a patient, classified in class 435/424, subclass 6/7.1/93.71.
- XIII. Claim 20, drawn to an isolated polynucleotide, classified in class 536, subclass 23.1.
- XIV. Claim 21, drawn to polynucleotide, classified in class 536, subclass 23.1.
- XV. Claim 22, drawn to polynucleotide, classified in class 536, subclass 23.1.
- XVI. Claim 23, drawn to polypeptide, classified in class 530, subclass 350.
- XVII. Claim 24, drawn to polypeptide, classified in class 530, subclass 350.
- XVIII. Claim 25, drawn to polypeptide, classified in class 530, subclass 350.

2. The inventions are distinct, each from the other because of the following reasons:

a. Inventions I-III, V-VI, VIII and XIII-XVIII and IV, VII, IX and X-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Groups I, VI and XIII-XV are drawn to polynucleotide which can be used for nucleic acid purification, Groups II, and XVI-XVIII are drawn to polypeptide which can be used for antibody production, Group III is drawn to an antibody which can

be used for protein purification, Group IV is drawn to fusion protein which can be used for polypeptide purification and Group VIII is drawn to an isolated T cell population which can be used for immune response.

b. Among the products groups I-III, V-VI, VIII and XIII-XVIII, there are polynucleotide, polypeptide, antibody, fusion protein and T cell population. Polypeptides and nucleic acids have distinct chemical structures and physical properties, the former composed of amino acids and the latter composed of nucleotides. Further, they have distinct utilities, such as use of nucleic acids in hybridization and use of proteins for enzymatic function. Antibody, which is protein, has its special chemical structure and usage, for example, ELISA. An isolated T cell population is a type of cells, which involves immune response. Therefore, the above inventions are novel and unobvious over each other.

c. Among Groups XIII-XV, each group and I, VI has different nucleic acid sequence. Thus they are different invention.

d. Among Groups II, and XVI-XVIII, each group has different polypeptide sequence. Thus they are different invention.

e. Inventions IV, VII, and IX-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, Group IV is for detecting the presence of cancer by using polypeptide, Group VII is for simulating T cell specific for a tumor protein, Group IX is for stimulating an immune response with polynucleotide,

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polypeptide, antibody, fusion protein and T cell population, Group X is for treating cancer in a patient with polynucleotide, polypeptide, antibody, fusion protein and T cell population, Group XI is for detecting the presence of cancer via hybridization and Group XII is for inhibiting the development of a cancer in a patient with polynucleotide, polypeptide, antibody, fusion protein and T cell population. Since they different modes of operation, different functions, or different effects as indicated above, they are distinct inventions.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. These claims are generic to a plurality of disclosed patentably distinct restriction groups comprising different SEQ ID NOs. Applicant is required under 35 U.S.C. 121 to elect no more than 1 disclosed nucleic acids or polypeptide sequence even though this requirement is traversed.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 703 (305) 7112. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung *J.T.*  
February 26, 2005

*Kenneth R. Horlick*  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

3/3/05